DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4500
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m3904r

June 16, 2000

WARNING LETTER NO. 2000-NOL-24

OVERNIGHT DELIVERY
FEDERAL EXPRESS

Mrs. Thanh T. Le, Owner
Mikes Seafood
516 South Lewis Street
New Iberia, Louisiana 70560

Dear Mrs. Le:

We inspected your firm, located at 516 South Lewis Street, New Iberia, Louisiana, on April 5, 6, 10, 14 & 20, 2000, and found serious deviations from Title 21 of the *Code of Federal Regulations*, Part 123 (21 CFR 123), Fish and Fishery Products (Seafood HACCP regulations). A Form FDA 483 (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your crabmeat and crawfish tailmeat produced in this facility to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov .

The deviations were as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (b). However, your firm does not have a HACCP plan for cooked, peeled crawfish tailmeat, packed in vacuum bags and stored under refrigeration, to control the food safety hazards of chemical contaminants and pesticides, *Clostridium botulinum* toxin formation during storage and distribution, and the growth and formation of other toxins as a result of time/temperature abuse;

- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for crabmeat does not correctly describe the cooking process and monitoring of critical limits;

- You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for crabmeat does not list the food safety hazards of pathogen growth and toxin formation associated with time/temperature abuse after cooking;

- You must implement the monitoring procedure listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure for time and temperature at the "cooking" critical control point (CCP) to control the "survival of pathogens" hazard listed in your HACCP plan for crabmeat;

- You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the critical limit of cooking temperature for crabmeat at the "cooking" CCP, as evidenced by lack of calibration of monitoring devices and lack of semi-annual finished product microbial testing; and,

- You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition and cleanliness of food contact surfaces, prevention of cross-contamination from insanitary objects, and exclusion of pests from the food plant with sufficient frequency to ensure control. This is evidenced by flies on cooked product; flies and spiders in the processing rooms; black residue from previous operations on the floors of both the cooked/finished product cooler and icemaker/storage facility; black residue on the ice chute leading into the ice storage facility; water dripping onto cooked product from spray hitting a wall encrusted with black and brown residue from previous operations; condensate from the cooling unit dripping onto cooked product in baskets; pitting and brown residue from previous operations on the surface of the cooking room cooked product cooling table; use of the boiling room cooked product cooling table without first cleaning and sanitizing; employees routinely touching insanitary objects such as the cooler door and then touching cooked product without first sanitizing their hands; insanitary processing equipment and packaging materials; and, numerous other conditions and practices which could lead to contamination of the finished product.

During the previous inspection on March 31 & April 1, 1998, and in a letter from FDA, dated May 28, 1998, you were notified of similar deficiencies as described in this letter. During the inspection and in the letter noted above, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in 24 months time, your firm has not taken action to correct these deficiencies.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the Form FDA 483. Please respond to this office in writing within three (3) weeks of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as: your revised HACCP plan, copies of your monitoring records, copies of corrective action data, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deficiencies in your plant. You are responsible for ensuring your firm operates in compliance with the Act, the Seafood HACCP regulations, and the Current Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have any questions regarding any issue in this letter, please contact Ms. Hardin at (504) 253-4519.

Sincerely,

for Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483